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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,381	09/10/2003	Kiyoshi Miyake	S0529.0006	3331
32172	7590 05/17/2005		EXAM	INER
	N SHAPIRO MORIN &	LEUBECKER, JOHN P		
1177 AVENUE OF THE AMERICAS (6TH AVENUE) 41 ST FL. NEW YORK, NY 10036-2714			ART UNIT	PAPER NUMBER
			3739	
•			DATE MAILED: 05/17/200	5

Please find below and/or attached an Office communication concerning this application or proceeding.

		Applic	ation No.	Applicant(s)			
		10/658	3,381	MIYAKE, KIYOSHI			
Office Action Summary			ner	Art Unit			
		John P	. Leubecker	3739			
Period fo	The MAILING DATE of this communica or Reply	ition appears on	the cover sheet with the c	orrespondence address			
THE I - Exter after - If the - If NO - Failu Any r	ORTENED STATUTORY PERIOD FOR MAILING DATE OF THIS COMMUNICATION of time may be available under the provisions of SIX (6) MONTHS from the mailing date of this communication of the period for reply specified above, the maximum statute to reply within the set or extended period for reply will eply received by the Office later than three months after ad patent term adjustment. See 37 CFR 1.704(b).	ATION. 7 CFR 1.136(a). In no cation. 8 reply within the ory period will apply an , by statute, cause the	event, however, may a reply be tim statutory minimum of thirty (30) days d will expire SIX (6) MONTHS from application to become ABANDONEI	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).			
Status							
1)[🗆	Responsive to communication(s) filed	on <u>18 February</u>	<u>2005</u> .				
2a) <u></u> ☐	This action is FINAL . 2b)⊠ This action is non-final.						
3)□	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Dispositi	on of Claims						
5)□ 6)⊠ 7)□							
Applicati	on Papers						
9)□ .	The specification is objected to by the E	xaminer.					
10)	0)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11)	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority u	nder 35 U.S.C. § 119		•				
 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☒ All b) ☐ Some * c) ☐ None of: 1. ☒ Certified copies of the priority documents have been received. 2. ☐ Certified copies of the priority documents have been received in Application No 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). 							
* See the attached detailed Office action for a list of the certified copies not received.							
Attachment	(s)						
1) Notice	e of References Cited (PTO-892)		4) Interview Summary	(PTO-413)			
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)			Paper No(s)/Mail Da				
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application (PTO-152) 6) Other:							

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "distal portion coupled to the distal end of the flexible portion" (lines 3-4 of claim 1) and the "proximal portion coupled to a proximal end of the flexible tube portion" (line 5 of claim 1) must be shown or the feature(s) canceled from the claim(s). Note that these "elements" also appear in claim 14. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

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2. The abstract of the disclosure is objected to because it amounts to a general statement as to what is known in the prior art and thus does not adequately or sufficiently apprise the reader of any inventive aspect described in the disclosure. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 4. Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As for claims 1 and 14, from which all other claims depend, these claims recite a "distal portion coupled to the distal end of the flexible tube portion" and the "proximal portion coupled to a proximal end of the flexible tube portion". As recited, these portions are located on either end of the flexible tube portion. The specification fails to adequately set forth as to what these elements are referring. Note page 11, lines 8-17 of the specification which describes that a head portion (2a1) is connected to a bendable portion (2a2) which in turn is connected to the flexible tube portion (2a3). Also, the proximal end of the flexible tube portion is connected to the operation section.

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Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the

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subject matter which the applicant regards as his invention.

6. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for

failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention.

As to claims 1 and 14, the specific connections between the flexible tube portion, the

distal portion, the bendable portion and the proximal portion make the claims indefinite, not only

because it is not clear as to what the distal and proximal portions are referring, but also because,

even if the distal and proximal portions can be attributed to certain disclosed structure, the

claimed structure does not appear to be describing what is disclosed. For the purposes of

examination, the claimed insertion section will be interpreted as, i.e., having a head portion, a

bendable portion and flexible tube portion, in that order.

As to claims 9 and 12, "the display portion" lacks antecedent basis.

As to claim 6, the term "below" is a relative term that is ambiguous without a frame of

reference.

As to claim 11, the term "downwardly" is a relative term that is ambiguous without a

frame of reference.

Dependent claims inherit those defects.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 8. Claims 1, 2, 4-9, 11 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshihashi (U.S. Pat. 4,750,475).

Yoshihashi disclose an insertion section including a head portion (22), a bendable portion (21) and a flexible tube portion (20), an operation section (10) coupled to the proximal end of the insertion section and including a grip portion (11) and a bending operation portion (14,15, col.2, line 61 to col.3, line 2), a instrument channel (49) in the insertion section that is open at the distal end and having a proximal opening located on the grip portion (Figure 2). As to claim 2, the grip portion has a display portion (32) connected thereto (through 30 and 31). As to claims 4 and 7, the proximal end of the instrument channel has a forceps-port constructing member (any of elements of Figure 3 that are connected to the proximal end of channel 49) and both are located on a rear surface of the grip portion (Figure 2). As to claim 5, grip (11) forms a casing that can be gripped. As to claims 6 and 11, and viewing the Figure 1 upside down, the display portion (32) is provided on an "upper" portion (as connected through cable 30) and the proximal open end of the instrument channel is located below the display portion and is downwardly facing (it is noted that the terms "upper", "below" and "downwardly" are relative terms that are given no frame of reference). As to claim 8, although it is not clear how it could interfere, the forcepsport constructing member does not interfere with operation of the bending operation portion

(note col.2, line 66 to col.3, line 2). As to claim 9, the forceps constructing member is located "near" the display portion and the bending operating portion (note Figure 1). All elements and limitations of claim 14 have been mentioned above.

Claim Rejections - 35 USC § 103

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 10. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshihashi in view of Nishigaki et al. (U.S. Pat. 4,905,082).

Yoshihashi discloses a universal cable (30) attached to the grip (11) but fails to disclose whether or not it is detachable from the grip (a detachable cable 30 would make the grip 11 detachable from the display portion). Nishigaki et al. demonstrate the level of ordinary skill in the art by showing that a detachable universal cable with the grip of the endoscope has been known and previously conceived. Note connector receptacle (269) (erroneously labeled as the right-most (259)) which detachably connects the imaging device (267) wires to a processor and monitor (note Figure 12). A detachable connection would clearly aid in cleaning the endoscope, allow modular connection between multiple endoscopes and cables, and prevent disposable of all components if one of the cable or endoscope malfunctions. Because of these obvious benefits, it

would have been obvious to one of ordinary skill in the art to have made the connection of the cable (30) to the grip (11) of the Yoshihashi device detachable.

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshihashi in view of Green (U.S. Pat. 5,928,137).

Yoshihashi discloses a monitor connected to the operation section by a flexible universal cable and thus fails to disclose that the monitor is directly, rigidly attached (in a detachable manner) to the proximal end of the endoscope. Green teaches to directly, rigidly attach (in a detachable manner) a monitor to the proximal end of an endoscope (note at least Fig.1) to improve the eye hand coordination of the surgeon by making the endoscopic surgery look and fell more light open surgery (col.1, line 58 to col.2, line 8). It would have been obvious to one of ordinary skill in the art to have detachably attached the monitor of Yoshihashi to the operation section for the reasons taught by Green, thus meeting the limitations of claim 12.

12. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshihashi in view of Ciarlei (U.S. Pat. 5,314,070).

Yoshihashi discloses the device as described above but fails to disclose a case for housing the device in a wound state. Ciarlei teaches a case (11) for housing an endoscope in a wound state to "provide a simple and reliable storage and transport case structure" (col.1, lines 57-60). It would have been obvious to one of ordinary skill in the art to have provided a case as claimed for the endoscope of Yoshihashi for the reasons taught by Ciarlei.

13. Claims 1-11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grabover et al. (U.S. Pat. 5,785,644) in view of Salvati et al. (U.S. Pat. 5,373,317) and further in view of Ebling et al. (U.S. Pat. 4,934,340).

Grabover et al. disclose a laparoscope insertion section (32), an operation section (50,82) coupled to the proximal end of the sheath having a grip portion (82), wherein the insertion section has a instrument channel (col.7, lines 52-59) open at the distal proximal ends, the proximal end located on the grip portion (Figs. 1 and 2). Grabover et al. disclose that the insertion section in this instance is rigid, which is common in laparoscopes, and thus fails to disclose a flexible insertion section having a flexible portion, a bendable portion, a distal end portion and a bending operation portion on the grip portion for bending the bendable portion. However, everything described above that Grabover et al. fail to disclose are conventional elements in a controllably bendable endoscope. For example, Salvati et al. disclose a substantially similar endoscope including a flexible portion (11), a bendable portion (13), a distal end portion (12) and a bending operation portion (20) on the grip portion (Fig. 1) for bending the bendable portion. Furthermore, bendable laparoscopes have been contemplated to provide guidability as taught by Ebling et al. (col.7, lines 30-39). Given the disclosed information as set forth above and the level of ordinary skill in this art, it would have been obvious to one of ordinary skill at the time the invention was made to have provided the necessary elements as discussed above to make the sheath of Grabover et al. bendable for the mere reason of increasing the ease of guiding the sheath to the desired location within the body.

As to claim 2, note display (70, col.8, lines 38-42). As to claims 3, 6 and 10, note housing member (50) which surrounds display (70)(see Figs. 2 and 3). This part of the housing

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is a frame to the display and the proximal open end of all the channels are "provided on" such frame on a side which is "below" the display. As to claim 4, reading the rear surface of the housing (50) as being part of the grip portion, claim 4 is met. As to claims 7-9, note forceps-port constructing member (62, 66 or 68). It is noted that when modifying the Grabover et al. device to include a bending operation portion, it is assumed that such modification will result in a device having operability and thus the forceps-port constructing member would "not interfere" with the operation of the bending operation portion. As to claim 11, pointing insertion section up (toward the sky) would provide a "downwardly opening forceps port formed in a lower end of the casing".

Response to Arguments

14. Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the new ground(s) of rejection. Rejections appearing above better characterize the Office's position with respect to patentability of the claims. Because new rejections have been made, this Office Action will not be made final.

Although a limited number of references were used above to show the Office's position with respect to the patentability of the claims, there are many other reference (cited below) that either anticipate or make obvious at least some of the claims. Applicant is requested to review all prior art that is cited by the Examiner and amend the claims to overcome all the cited prior art, not just the ones used in the rejections.

Conclusion

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15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following is a partial listing of references that appear to be extremely relevant to Applicant's claims by showing at least an proximal instrument opening on the operation section (handle) of the endoscope.

Seigmund (U.S. Pat. 4,598,698)	Furihata (U.S. Pat. 3,897,775)
Krauter et al. (U.S. Pat. 4,649,904)	Morris et al. (U.S. Pat. 4,874,364)
Renaud (U.S. Pat. 4,984,563)	Rossoff (U.S. Pat. 5,183,031)
Rovegno (U.S. Pat. 6,315,712)	Adair (U.S. Pat. 5,873,814)
Komi et al (U.S. Pat. 5,971,917)	Ouchi (U.S. Pat. 6,210,378)
Green (U.S. Pat. 6,221,007)	Wood et al. (U.S. Pat. 5,701,155)
Shishido (U.S. Pat. 4,700,694)	

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Leubecker whose telephone number is (571) 272-4769. The examiner can normally be reached on Monday through Friday, 6:00 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)

John P. Leubecker Primary Examiner

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jpl